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Case No: FD13P02273

IN THE HIGH COURT OF JUSTICE
FAMILY DIVISION

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 06/03/2014

Before :

MRS JUSTICE HOGG

- -

Between :

ELIZABETH WARREN	**Claimant**
- and -	
(1) CARE FERTILITY (NORTHAMPTON) LIMITED **(2) HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY**	**Interested Parties**

- -
- -

Miss Jenni Richards QC, Miss Catherine Dobson Counsel for the **Claimant**
Miss Jane Collier Counsel for the **Interested Party**

Hearing dates: 31 January 2014

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

MRS JUSTICE HOGG

This judgment was delivered in open court.

The judge has given leave for this version of the judgment to be published on condition that (irrespective of what is contained in the judgment) in any published version of the judgment the anonymity of the children and members of their family must be strictly preserved. All persons, including representatives of the media, must ensure that this condition is strictly complied with. Failure to do so will be a contempt of court.

MRS JUSTICE HOGG :

1. The application before me is one for a declaration that it is lawful for the sperm of Warren Brewer who died on 7 February 2012 to be stored beyond 18 April 2015, and for a period of up to 55 years until 18 April 2060, so that it can be used by the Claimant Elizabeth Warren, his widow, for the purposes of conceiving a child or children.

2. Although there are two Interested Parties I have heard only from one of them. The Clinic being the Care Fertility (Northampton) Ltd. [CARE] which is currently storing Mr Brewer's sperm, although served and aware of these proceedings has played no part. I have heard Counsel on behalf of the Human Fertilisation and Embryology Authority [HFEA] and read the statement and exhibits of Peter Thompson, the Chief Executive of HFEA.

3. I heard Leading Counsel on behalf of Mrs Warren, read Mrs Warren's statement and heard her in evidence. I have also read the statements of both her parents-in-law who are supporting her in her application.

<u>The Factual Background</u>

4. Mrs Warren is now 28 years old. She is the widow of Mr Warren Brewer who died on 9 February 2012 aged 32.

5. They met in April 2004, and began a relationship soon afterwards; she was then nearly 19 and he was 25. From that time until Mr Brewer's death they were inseparable and their relationship developed and deepened.

6. Mr Brewer was a ski instructor and seemingly a healthy, fit young man.

7. In February 2005 Mr Brewer began to suffer occipital headaches. He was diagnosed with a posterior fossa brain tumour and referred to the John Radcliffe Hospital, Oxford where he underwent a craniotomy. Following the craniotomy he was treated with high doses of cranio-spinal radiotherapy.

8. One of the known side effects of such treatment was a high risk of sub-fertility or infertility.

9. Thus, in about April 2005 and before he commenced radiotherapy, Mr Brewer was referred by his then Consultant to the CARE clinic in Northampton so that samples of his sperm could be taken, frozen and stored to enable him to have children in the likely event he became infertile as a consequence of the radiotherapy.

10. On 12 April 2005 Mr Brewer attended the CARE clinic and signed a standard consent form provided by CARE and entitled 'CARE Consent for Sperm Storage'. By this document he consented to the sperm being stored for a period of three years (up to April 2008). It seems that this period was dictated by the CARE clinic's policy, which was to offer storage for the period for which NHS funding was available. At that time Mr Brewer did not consent for the use of the sperm in the treatment of a named partner. He also indicated that in the event of his death or becoming mentally incapacitated his sperm should be allowed to perish.

11. In addition to the Consent form I have seen a note of the meeting at the clinic recorded by J. Byrne RGN, who countersigned the Consent form. In the attendance note there is a clear reference to a medulloblastoma being removed at Oxford, and to radiotherapy due to commence in May. It is recorded: "Would like to store sperm". "Does not have a partner". There is no reference to counselling being given or offered although there is a note "Sperm freeze info" with a tick beside it.

12. Between 12 April and 6 May 2005 twelve vials of Mr Brewer's sperm were collected, frozen and stored at the CARE clinic where they have remained ever since. Soon afterwards Mr Brewer underwent radiotherapy treatment.

13. In September the claimant and Mr Brewer moved to Leeds and started to live together. Mr Brewer was still recovering from surgery and treatment.

14. In February 2006 Mr Brewer was able to return to work as a ski and snowboard instructor. An MRI scan showed no return of the brain tumour.

15. On 4 May 2006 CARE wrote to Mr Brewer indicating that if he no longer wanted them to store his sperm he should authorise them to dispose of it. In response to that letter he wrote on 25 May 2006 that he wished CARE to continue storing the sperm for another 12 months, referring to a previous telephone call when it had been discussed.

16. In advance of the expiry of the original consent CARE made contact and arranged an appointment for him to visit the clinic. At that appointment on 11 January 2008 he completed two consent forms provided to him by the clinic.

17. He signed an MS form which had been produced by HFEA in which he consented to storage of sperm for a period of 4 years, and that in the event of his death storage should continue for later use, but if he became mentally incapacitated it should be allowed to perish. This part of the form headed "Posthumous storage" is not specifically time limited.

18. He also signed an MT form, again produced by HFEA, in which he named his partner, Mrs Warren, under her maiden name, and consented to the use of his sperm in her treatment for creating embryos in vitro and for the use of those embryos in her treatment. That consent was not time limited. He also gave his consent for his name and details to be entered on the birth certificate of any child resulting from such fertility treatment to his partner after his death.

19. By this time Mrs Warren and Mr Brewer had discussed plans for marriage and children. On his return from the clinic he told Mrs Warren that he had filled in the consent forms for storage and naming her as his partner for treatment, and for posthumous use of the sperm in her treatment. They discussed this latter possibility and it was clear to Mrs Warren that Mr Brewer to quote her:

> "had thought about it and was happy with the idea of his children never meeting him, and he was happy that if having his children was something I wanted"

20. On 20 March 2009 Mr Brewer signed a further MS form provided by CARE with a storage period of 6 years, and for the continued storage for later use in the event of his mental incapacity or death. In addition he signed a consent form for the disclosure of identifying information about fertility treatment in which he named his General Practitioner, Mrs Warren and his oncologist.

21. In respect of the storage period on both MS forms Mrs Warren says, and there is no evidence to the contrary, that the figure 4 or 6 had been written in by the clinic, and that Mr Brewer was never given the opportunity to consent to a longer or different period. She says that the clinic prescribed the time period which was set by the local PCT funding policy.

22. It is to be noted that each form, just above the time period, states:

> *"Normally the law allows you to store your sperm for 10 years. In certain circumstances the storage period can be extended. Your health care practitioner will be able to explain whether you can do this, and for how long you may be able to store your sperm."*

23. Then appears:

> *"I consent to the storage of my sperm (please tick and complete one of the following options):*
>
> *i) for 10 years;*
>
> *ii) for a period other than 10 years please state the storage period of years."*

It was here that the clinic inserted 4 or 6 and it was this option he ticked.

24. There is no evidence to say that Mr Brewer received an explanation from CARE as to the "certain circumstances" and if applicable how he could extend the storage period beyond 10 years.

25. Moreover it could be argued that it was not clear from what date the period of storage ran, whether from the original date of storage in 2005 or whether from the date of the form.

26. In February 2010 Mr Brewer became unwell again. He underwent an MRI scan on 16 March and was admitted to the John Radcliffe Hospital two days later. He was diagnosed with a further tumour and underwent further surgery.

27. In August 2010 Mr Brewer was advised that due to the return of the tumour he had less than 5% chance of being alive in 5 to 10 years.

28. In October 2010 Mr Brewer and Mrs Warren became engaged to be married.

29. On 7 December 2010 CARE wrote to inform Mr Brewer his consent for storage would expire on 19 April 2011 and that he could extend the storage period for a "further 2 years" by completing and returning the CARE Decision Form. He was informed that CARE was seeking further funding for the storage from his local PCT, failing which he would be responsible for their fees.

30. On the Decision Form Mr Brewer ticked the box for: *"Storage. Please maintain storage of my frozen sperm*" and this included all the samples of sperm. It was not time limited. He signed and dated the form 13 December 2010 and gave his new address in Birmingham.

31. On 26 January 2011 CARE wrote to the appropriate Primary Care Trust in Birmingham for funding up to March 2013.

32. On 25 March 2011 CARE wrote to Mr Brewer confirming funding by the PCT for another year, sending and requesting he fill in the HFEA LGS form which "will allow your sperm to remain in storage until 19 April 2012".

33. On the form, at the heading, entitled "Your consent to extending the storage of your eggs or sperm" there are printed various notes. Under the heading there appears the following:

> *About this form.*
>
> *Who should fill in this form?*
>
> *Fill in this form if you have eggs or sperm in storage and wish to extend your current storage period.*
>
> *You can consent to the storage of your eggs or sperm for up to 55 years. If you wish to store your eggs or sperm for more than 10 years either yourself, your partner, or someone to whom your eggs or sperm have been allocated to must meet medical criteria.*
>
> *A medical practitioner must certify that the medical criteria are met when the storage period extends beyond the initial 10 years and subsequently every 10 years for the duration of storage. The medical practitioner's statement(s) should be attached to this form.*
>
> *How do I know if I am eligible?*
>
> *For eggs or sperm to be stored for longer than 10 years:*
>
> *– the eggs or sperm provider or*
>
> *– the person to whom the eggs or sperm have been allocated to must have or be likely to develop premature infertility.*
>
> *Why do I have to fill in this form?*
>
> *Under the Human Fertilisation and Embryology Act 1990 (as amended) you need to give your consent in writing if you want your eggs or sperm to be stored.*
>
> *You can make changes to or withdraw your consent to storage at any time. If you would like to change or withdraw your consent you should ask your clinic for new forms.*
>
> *Before filling in this form your clinic should make sure you receive all the relevant information you need about extending the storage period of your eggs or sperm. You should also have been given an opportunity to receive counselling about this.*

34. On the following page, entitled "Storing eggs or sperm", are printed further notes:

> *For how long do you consent to your eggs or sperm being stored?*

> *You can consent to the storage of your eggs or sperm for up to 55 years. Your eggs or sperm may only be stored for more than 10 years if you or someone to whom your eggs or sperm have been allocated (including your partner) is prematurely infertile or is likely to become prematurely infertile. A medical practitioner must certify in writing that the medical criteria have been met. Where the criteria have been met the storage period will be extended from the date the criteria are met. The storage period can then be extended by further 10 year periods if it is shown at any time within each extended storage period that the criteria continues to be met. There is a maximum period of 55 years. The medical practitioner's statement(s) should be attached.*

35. There then appears two boxes for ticking, one for 10 years, and one for a specific period (up to a maximum of 55 years) and "specify the number of years". The clinic had filled in the latter box with a typed X and filled in a further box with 7 for the number of years.

36. It was raised in argument before me whether this meant 7 years from the date of original storage, or the date of this document.

37. Mr Brewer signed this page on 14 April 2011.

38. On the following page he also signed and dated the Declaration:

> *I declare that*
>
> *- before I completed this form I was given information about the different options set out in this form, and I was given an opportunity to receive counselling*
>
> *- the implications of giving my consent, and the consequences of withdrawing this consent have been fully explained to me, and*
>
> *- I understand that I can make changes to or withdraw my consent to storage at any time until the eggs or sperm (or embryos created from them) have been used or allowed to perish.*
>
> *I declare that the information I have given on this form is correct and completed.*
>
> *I understand that information on this form may be processed and shared for and in connection with the conduct of licensable activities under the Human Fertilisation and Embryology Act 1990 (as amended) in accordance with the provisions of that Act.*

39. There is no evidence before me to say other than the form and covering letter from CARE, to which I have referred that the Clinic gave Mr Brewer any further relevant information as to the various options he had and what he needed to do to ensure the storage of his sperm for any extended period. The covering letter merely said: The form "will allow your sperm to remain in storage until 19 April 2012. Should you wish to extend this the fee is £155 per year".

40. There was an offer to him to telephone if he had any queries but no offer to receive counselling or any relevant information.

41. From the documents it is apparent he was given the form with the box already marked and 7 years entered in the box, with no proper information being given or options explained; thus although he signed the Declaration he did not in fact receive information about the options nor was he given an opportunity to receive counselling.

42. Furthermore, the LGS form did not allow the provider of the sperm or eggs to stipulate what should happen in the event of his death or mental incapacity.

43. On 14 April 2011 Mr Brewer also completed the CARE Change of Details form naming Mrs Warren and giving the address of the flat he and she had recently purchased in Birmingham.

44. On 27 April 2011 CARE wrote to Mr Brewer enclosing a HFEA MT form to be signed and dated. It seems he never received it.

45. A further letter together with another HFEA MT form was sent on 18 May 2011.

46. On 17 August 2011 CARE wrote again saying that they had not received from him a completed HFEA GS consent form, and purportedly sent a copy of that form to be completed urgently.

47. What in fact was sent was a HFEA MT form.

48. It was a printed form with various notes at the top of page 2 which was entitled "Your consent to the use and storage of your sperm and embryos for your partner's treatment".

> *Who should fill in this form?*
>
> *Fill in this form if you are a man, and your partner is receiving treatment using embryos created in vitro with your sperm.*
>
> *Why do I have to fill in this form?*
>
> *Under the Human Fertilisation and Embryology Act 1990 (as amended) you need to give your consent in writing if you want your sperm or embryos created in vitro with your sperm to be used or stored. You will need to decide what will happen if you die or lose the ability to decide for yourself (become mentally incapacitated).*
>
> *You can make changes to or withdraw your consent at any point until the time of embryo transfer or the use of embryos in research in training. If you would like to change or withdraw your consent you should ask your clinic for new forms.*
>
> *Before you fill in this form your clinic should make sure that you receive all the relevant information you need about your and your partner's treatment. You should also have been offered counselling about the implications of having treatment.*

49. At the bottom of page 1 he completed the details about himself and filled in details about "his partner" being Mrs Warren, identified in her maiden name.

50. On page 2 he consented to his sperm being used to create embryos in vitro for his partner's treatment.

51. He also consented to the embryos (created in vitro with your sperm) being stored.

52. Then appears further printed notes:

> *For how long do you consent to the embryo (created in vitro with your sperm) being stored?*
>
> *You can consent to the storage of your embryos for up to 55 years. Your embryos may only be stored for more than 10 years if you or someone to whom your embryos have been allocated to (including your partner) is prematurely infertile or is likely to become prematurely infertile. A medical practitioner must certify that the medical criteria has been met.*

Where the criteria have been met the storage period will be extended by 10 years from the date the criteria are met. The storage period will be extended by further 10 year periods if it is shown at any time within each extended storage period that the criteria continues to be met. There is a maximum storage period of 55 years. The medical practitioner's statement(s) should be attached to this form.

53. There are 3 boxes, one which required ticking: one for 10 years, one for 55 years, and one, which he ticked, for a specific period (up to a maximum of 55 years). In the relevant box 7 was inserted. Mrs Warren states, and it is not disputed, the figure 7 had already been written into that box by CARE. He declined his consent for his sperm or embryos to be used for research projects or training purposes.

54. On page 3 he consented to his sperm being used to create embryos in vitro for his partner's treatment in the event of his death, or him losing mental capacity. He also consented to embryos (already created in vitro with your sperm) being used for his partner's treatment. Mrs Warren said although there were at that time no embryos they filled in that part of the form for fear of being 'caught out on a technicality'. This page was signed by Mr Brewer and dated 23 August, whereas the other pages had been dated 22 August.

55. On page 4 he gave his consent to being registered as the legal father of any child born to his partner following treatment after his death.

56. On the final page he signed the declaration, in similar terms as the previous LGS form. Again, there is no evidence he received any offer of counselling, or any further information as to the different options from the clinic.

57. Some time in 2011, the clinic's note recording the conversation is undated. It records "that Mr Brewer wanted to confirm that we (the clinic) have all the necessary consent forms in place to allow Mrs Warren to use the sperm to achieve a pregnancy in the event of his death".

58. On the 9 December 2011 Mrs Warren's brother died in a car crash, which understandably caused her and the family considerable distress.

59. On 18 December 2011 Mr Brewer's health deteriorated and following an MRI scan the Consultant Oncologist informed Mrs Warren the tumour had spread extensively and no further oncology treatment was available. He was admitted to a hospice with days, weeks or months only to live.

60. On 22 December 2011 CARE again wrote to Mr Brewer indicating the storage period was due to expire on 19 April 2012, and that he could extend the period for a further two years by completing and returning the enclosed CARE Decision Form and informing him CARE was seeking further funding from his PCT.

61. On 29 December 2011 Mr Brewer and the claimant married at the hospice.

62. On 2 January 2012 Mr Brewer completed the CARE Decision form. He ticked 'Storage. Please maintain storage of my frozen sperm'. The form was silent as to duration of the storage.

63. Mr Brewer died on 9 February 2012.

64. On 27 February 2012 CARE wrote to Mr Brewer enclosing an HFEA LGS form for completion to extend the storage of his sperm. CARE was unaware of his death.

65. Mrs Warren spoke to CARE on 2 March from which she understood that the clinic had no records of her on their computer or of Mr Brewer's consent for her to use his sperm after death, which clearly distressed her greatly.

66. Thereafter CARE approached the Authority for advice, as did Mrs Warren on her own account.

67. After some consideration the HFEA wrote to Mrs Warren's solicitors on 16 July 2012, "on further analysis the Authority accepts that a reasonable interpretation of the consent form is that the period of 2 years in the accompanying letter (22 December 2011) does not represent a specification by the gamete provider of a storage period less than the statutory storage period" which being 10 years would enable the sperm to remain in storage until 18 April 2015.

68. If this were the case, in order to achieve a pregnancy Mrs Warren would have to commence treatment in early 2014. To date she is still grieving for her husband and brother, is trying to rebuild her life and commence employment as a physiotherapist for which she has just completed her training. She tells me she does not feel ready at this time to contemplate trying to start a family from emotional, financial, practical and professional reasons.

69. What is of great interest following on from the circumstances of this case HFEA on 31 May 2012 issued Guidance to Licensed Clinics entitled "Extension of storage of Gametes and embryos where one of the gamete providers is deceased".

70. The document does not give specific advice to clinics, but gives a warning.

> "The law is clear gametes and embryos should only be stored when there is effective consent. The HFEA has no powers to authorise extended storage when the consent provisions laid out in the 1990 Act have not been complied with."
>
> "HFEA Directions specify that consent must be provided on a designated form to ensure that consent is properly taken and understood. The HFEA form provides an opportunity for a gamete provider to document their consent in relation to possible scenarios, including posthumous parenthood. In the absence of information a gamete provider's consent may not be clear which could impact on the future use of the gametes:"
>
> "In our experience these situations are more likely to arise where patients are routinely asked to restrict their storage to a period of only two or three years. We know that centres ask patients to do this either to encourage them to maintain regular contact to avoid gametes and embryos being stored longer than the patient need them to be or, on occasion, to ensure that payment for ongoing storage is required. If your centre asks patients to restrict their storage to a period less than the

> maximum permitted by the law there is a higher risk that in the event of a patient dying the gametes or embryos cannot continue to be stored causing significant distress. We strongly encourage you to consider the impact of this practice particularly in circumstances where individuals have life-threatening illness."

71. The guidance goes on to urge centres encountering difficulties such as in this case to seek legal opinion. The guidance is signed by Mr Thompson, the Chief Executive.

72. On 17 April 2013 Mr Brewer's Consultant Oncologist Dr David Spooner at The Queen Elizabeth Hospital, Birmingham, wrote to Mrs Warren's solicitors indicating that he was grateful to his colleagues in Oxford:

> "for their foresight in obtaining sperm banking prior to Mr Brewer's oncology treatment. The risk of male sub and infertility caused by craniospinal radiotherapy and cytotoxic chemotherapy is widely understood. Almost certainly the exit dose from the interior border of a craniospinal field would be associated with some form of azospermia. The concern is that surviving sperm could well be affected by low dose (mutrogenic) effects of radiotherapy, i.e even as low as 1.2 Gy cumulative dose. In addition whole brain radiotherapy is associated with endocrine dysfunction".
>
> "When I first met Warren (in 2010) I was aware of his intention to start a family and I strongly encouraged them not to try to conceive during the treatment with Etoposide because of the effect on total spermatogenesis; there is a very real risk of mutogenesis. We hoped that Warren's condition would have improved to such an extent that he would have been able to use his sperm for IVF treatment."
>
> "I know that it was the prospective risk of both Warren and Beth together that his sperm should be preserved and that every attempt should be made for Beth to conceive after Warren's death, using his sperm. I am strongly and unequivocally in support of this ……"

73. In their solicitors letter dated 4 July 2013 the Authority acknowledged in terms that this letter satisfied the requirements of paragraph 4(3)(b) of the 2009 Regulations. I add it should have read paragraph 7(3)(b). However, on 16 January 2014 the Authority's solicitors again wrote resiling from their former acknowledgement that paragraph 4(3)(b) was satisfied in that the wording of the paragraph was "is prematurely infertile or is likely to become prematurely infertile", thus suggesting that it was intended that the gamete provider must be alive in order for a medical practitioner to issue an opinion about the person's fertility.

74. That remains the position before me, although Counsel for HFEA accepted that the content otherwise of Dr Spooner's letter would be sufficient to meet the requirement under Regulations 4(3)(b) or 7(3)(b). The HFEA maintains that the 2009 Regulations

and the LGS Form do not envisage the provision of a retrospective or posthumous opinion. In Section 5 of the Code of Practice under paragraph 17:16 there is guidance to a clinic that before consent is obtained from "anyone who wishes to store gametes for more than 10 years the centre should ensure that the conditions for extended storage are satisfied". One of these requirements is the provision of medical opinion, under paragraphs 4(3)(b) or 7(3)(b) of the Regulations.

75. In their letter of 16 January 2014 the solicitors added that it would be helpful to have the benefit of the determination of the Court on this issue.

Conclusions

76. I am able to draw some conclusions from the evidence provided by Mrs Warren and the documents produced by CARE:

1. Mrs Warren and Mr Brewer having met and developed a strong relationship were a devoted couple, and wanted to be life long companions and have and raise their own children;

2. Mr Brewer was made aware that if he were to receive radiotherapy there was a likelihood of him becoming infertile;

3. Mr Brewer, even before the relationship developed sufficiently to declare Mrs Warren his 'named partner', wanted to preserve his sperm to enable him to become a father in due course. With that in mind sperm was stored in April 2005;

4. By 2008 the relationship had developed and deepened and there were discussions between the couple that in the event of his death Mr Brewer wanted Mrs Warren to have the opportunity to have his child, or children, if she so wished. There was no time limit to this in his mind;

5. Over time this wish was conveyed to his parents and to Dr Spooner;

6. From the documentation provided by CARE there is no evidence to indicate Mr Brewer was given any information as to the law and regulatory requirements in respect of the length of time sperm could be stored either in April 2005 or following 1 October 2009 upon the 2009 Regulations coming into force;

7. The letters from CARE refers to "a further 2 years", and largely relate to provision of payment of their fees. The letters sent to Mr Brewer do not clarify his rights or options as required by the Code of Practice, and referred to in the HFEA LGS forms;

8. I accept Mrs Warren's evidence that on such forms as she saw which had been sent to Mr Brewer by the clinic the number of years had been inserted by the clinic prior to Mr Brewer signing the forms;

9. CARE failed to provide relevant information to Mr Brewer as to the options available to him and the necessary requirements of him, and failed to give him any option other than to consent for a specified number of years less than 10 years.

It may be that other clinics have fallen into the same trap, and the mischief which the HFEA sought to avoid in its Guidance of 31 May 2012;

10. As a consequence Mr Brewer was not provided with an explanation and information as to his rights and options, or regulatory requirements when he came to sign the various consent forms, particularly those post 1 October 2009;

11. I am satisfied from the written evidence produced on behalf of Mrs Warren and her own oral evidence that had he have known fully of his options and the requirements Mr Brewer would have consented to his sperm being stored for a period in excess of 10 years, up to a maximum of 55 years, and would have obtained the necessary medical opinion required under the 2009 Regulations. I am satisfied it was his wish that Mrs Warren should have the opportunity to have the use of his sperm after his death in order to have his child or children if she so wanted, and he would have done everything required of him to achieve this.

The Legal Framework

77. The Human Fertilisation and Embryology Act 1990 ("The Act") is the primary legislation which, inter alia, regulates the storage and use of gametes and embryos. Their storage and use are regulated by a licensing system the essence of which is provided for in the Act, and the subsequent secondary legislation the Regulations.

78. The establishment of The Human Fertilisation and Embryology Authority (HFEA) is provided for by Section 5 and Schedule 1 of the Act. Section 8 provides for "The General functions of the Authority" in particular by Section 8(1)(c):

> *"to provide advice and information for persons to whom licences apply, or who are receiving treatment services or providing gametes as embryos for use, and 8(1)(cb) to promote …… compliance with:"*
>
> *(i) requirements imposed by or under this Act, and*
>
> *(ii) the code of practice under Section 25 of this Act, and*
>
> *(d) to perform such other functions as may be specified in regulations.*

79. Section 4 provides that no person shall store any gametes or use any sperm except in pursuance of a licence, which under Section 11 may be granted by the Authority in accordance with the provisions of Schedule 2 of the Act.

80. There are various subsequent sections setting out provisions for the granting, revocation, suspension and variation of such licences by the Authority.

81. The general conditions of any licences are set out in Sections 12 and 13 which refer to Schedule 3, and the need to comply with the provisions of that Schedule.

82. I note an important safeguard is built into the Act under Section 13(5) whereby:

> *"A woman shall not be provided with treatment services unless account has been taken of the welfare of any child which may be born as a result of the treatment, including the need of that child for supportive parenting, and of any other child who may be affected by the birth."*

83. Thus the welfare of a child yet to be created by treatment must be considered before any treatment, whether or not the treatment is before or after the death of the sperm provider.

84. Section 14 adds further safeguards Section 14(1)(a)(i) *"the gametes of a person shall only be stored if received from that person"* and Section 14(c) *"gametes shall not be kept in storage for longer than the statutory storage period, and if stored at the end of that period shall be allowed to perish"*.

85. By Section 14(3) the statutory storage period in respect of gametes is such period not exceeding ten years; but, by Section 14(5) Regulations may provide that subsection (3) shall have effect as if for ten years .. there were substituted:

> (*a) such shorter period, or*
>
> *(b) in such circumstances as may be specified in the regulations such longer period.*

86. Section 25 provides for the Authority to maintain a Code of Practice

> *(1) Giving guidance about the proper conduct of activities carried on in pursuance of a licence under the Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.*
>
> *(2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services;*
>
> *(2A) The code shall also give guidance about:*
>
> *(a) the giving of a suitable opportunity to receive proper counselling, and*
>
> *(b) the provision of such relevant information as is proper.*
>
> *(6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but*
>
> *(a) The Authority shall in considering whether there has been any failure to comply with any condition of a licence and conditions requiring anything to be "proper" or suitable take account of any relevant provision of the code, and*
>
> *(b) The Authority may where it has power to do so whether or not to vary or revoke a licence takes into account any observations of a failure to observe the provisions of the code.*

87. Section 28(5A) was added by The Human Fertilisation and Embryology (Deceased Father) Act 2003. It enables a sperm provider to be treated as a father even if the sperm was used after his death:

> *(5A) If*
>
> *(a) a child has been carried by a woman is the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,*

(b) the creation of the embryo carried by her was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in the woman after his death,

(c) the woman was a party to a marriage with the man immediately before his death,

(d) the man consented in writing (and did not withdraw his consent)

(i) to the use of his sperm after his death which brought about the creation of the embryo carried by the woman or to the placing in the woman after his death of the embryo which was brought about by using his sperm before death, and

(ii) to being treated for the purpose in subsection (5l) as the father of any resulting child;

(e) the woman has elected in writing not later than the end of the period of 42 days from the day the child was born for the man to be treated for the purpose mentioned in (5l) as the father of the child, and

(f) no one else it to be treated as the father of the child by virtue of subsection (2) or (3) … then the man shall be treated for the purpose mentioned in subsection (5l) as the father of the child.

(5B) …..to ……..(5H) not applicable.

Subsection (5I) provides the purpose referred to in subsection 5A …. is the purpose of enabling the man's particulars to be entered in the particulars of the child's father in a register of live-births or still-births kept under the Births and Deaths Registration Act 1953, or Section 45 of the Act makes provision for the Secretary of State to make regulations under the Act.

88. Schedule 3 of the Act carries the title "Consents to use or storage of Gametes, Embryos or Human Admixed Embryos" etc.

89. *Paragraph 2 (2) provides:*

A consent to the storage of any gametes, any embryo or any human admixed embryo must:

(a) specify the maximum period of storage (if less than the statutory storage period);

(b) except in a case falling within paragraph (c) state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable because the person lacks capacity to do so to vary the terms of the consent or to withdraw it, and

(c) …… not applicable, and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation in vitro of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the persons death.

Under paragraph 3:

(1) Before a person gives consent under this Schedule:

(a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and

(b) he must be provided with such relevant information as is proper.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4.

Paragraph 4

(1) the terms of any consent under this Schedule may from time to time be varied and the consent may be withdrawn by notice given to the person keeping the gametes, human cells, embryo or human admixed embryo to which the consent is relevant.

Paragraph 5:

(1) A person's gametes must not be used for the purposes of treatment service unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

Paragraph 8:

(1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.

90. Regulations were made under Section 14(5) and Section 45 of the Act in 2009, coming into force on 1 October 2009. The full title of the Regulations are The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009.

91. Under Regulation 4 provision is made for "Extension of statutory storage period for premature infertility":

(1) For the purpose of this regulation – "relevant period" means ten years from the date that:

(a) the gamete in question was first placed in storage; or

(b) if later, the most recent previous written opinion was given under sub-paragraph (3)(b).

(2) In the circumstances specified in paragraph 3 the maximum storage period for a gamete shall subject to paragraph 4 be the period beginning with the date on which the gamete was first placed into storage and ending ten years after the date of the most recent written opinion given under subparagraph (3)(b).

(3) The circumstances referred to in paragraph (2) are that:

(a) the person who provided the gamete in question has consented in writing to the gamete being stored for a period in excess of ten years for the provision of treatment services, and

(b) on any day within the relevant period a registered medical practitioner has given a written opinion that the person who provided the gamete or where they are not that person, the person to be treated is prematurely infertile or is likely to become prematurely infertile.

(4) Where the maximum storage period calculated in accordance with paragraph (2) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

92. Regulation 7(1) applies to any gamete that is in storage on the date the Regulations came into force, being 1 October 2009, and which therefore apply to Mr Brewer's gametes,

(2) Where paragraph 1 applies the maximum storage period for any gamete shall be

(a) subject to paragraph 5, where the circumstances in paragraph (3) are met the period beginning with the date on which the gamete was first placed in storage and ending ten years after the date of the most recent written opinion given under sub-paragraph (3)(b) or

(b) ten years where those circumstances are not met.

(3) The circumstances referred to in sub-paragraph (2)(a) are that

(a) the person who provided the gamete in question has consented in writing, whether before or after coming into force of these Regulations, to the gamete being stored for a period in excess of ten years for the provision of treatment services; and

(b) on any day within the relevant period but after the coming into force of these Regulations, a registered medical practitioner has given a written opinion that the gamete provider …… is prematurely infertile or is likely to become prematurely infertile.

(4) For the purposes of paragraph (3)(b) the relevant period means ten years from the date that

(a) the gamete in question was first placed in storage; or

(b) if later the most recent previous written opinion was given under sub-paragraph (3)(b).

(5) Where the maximum storage period calculated in accordance with the sub-paragraph (2)(a) would be greater than fifty five years, the maximum storage period for the purpose of that paragraph shall be fifty five years.

Summary

93. From reading the relevant sections of the Act, and the relevant 2009 Regulations a number of matters have become apparent:

1. As long ago as 1990 Parliament accepted that gametes and embryos could legally and properly be collected and stored to be used at a later date to create a child.

2. That such activities needed to be prescribed and regulated by statute and regulations. Safeguards and prohibitions were required to ensure that proper arrangements were in place and managed and such have been in place under the Act and relevant Regulations.

3. Since 1990 the Act and Regulations have been amended, and in particular S.28 was amended by the H F & E (Deceased Fathers) Act 2003. By those amendments it was specifically envisaged, and provided for, that the sperm of a man collected before his death could be used to create an embryo, and that any child born of that creation could be recognised and registered as the child of the deceased. The importance of the amendment is that Parliament accepted that medical science had progressed, and thought fit to enable with safeguards to make it lawful to create an embryo using the sperm of a deceased man.

4. There are basic issues about which the parties before me agree:

(i) gametes cannot be stored without consent of the provider;

(ii) consent for storage of gametes must be given in writing and signed by the gamete provider. There is no prescribed form;

(iii) there is a statutory storage period (ten years) but a gamete provider must specify the maximum period of storage if less than 10 years;

(iv) the consent must also include what is to happen to the gametes in the event of his death, or mental incapacity, whether they should perish at the end of the stated period or remain in storage;

(v) the 2009 Regulations provided circumstances in which gametes could be stored beyond 10 years from first storage with a maximum of fifty five years.

(vi) gametes may only be used for treatment purposes but only if the provider gives consent, in which case he may identify a particular person to receive the treatment.

(vii) before a person gives consent he must be given the opportunity to receive proper counselling, and be provided with such relevant information as is proper. That is set out in the statute, and provision made for guidance on this subject to licence holders in the Code of Practice.

Discussion

94. I have already said that there is no evidence to show what counselling was offered to Mr Brewer in 2005 or at any time, but more importantly there is no evidence to say that he was provided with the relevant information either in 2005, and particularly after 1 October 2009 when the 2009 Regulations came into being. That obligation was prescribed by statute, and is the duty of the CARE clinic.

95. Mr Brewer had always given his consent to the storage of the gametes when asked to do so. He had also named Mrs Warren as the person to use his gametes in her treatment and consented that in the event of his death his sperm could be used by her, and he be named the father of any child so created. Those later consents are not time limited. His intentions were clear to Mrs Warren, his parents and his consultant oncologist. Unfortunately, he did not give his written consent as required by the Regulations 4(3)(a) or 7(3)(a) to the gametes being stored for a period in excess of ten years for the provision of treatment services.

96. Given his known wishes and intentions one may well ask why not? The simple answer he was never given the opportunity by the clinic to do so. The forms he completed and signed had already been partially filled in by the clinic limiting the time for storage. He was not given the relevant information, nor the opportunity to complete a form which would have enabled him to opt for a period in excess of 10 years.

97. I am in no doubt that had he had the relevant information and the opportunity he would have consented to a period beyond 10 years.

98. I am also in no doubt that had he been informed by the clinic in clear terms that by Regulations 4(3)(b) or 7(3)(b) a medical practitioners written opinion as to his infertility or likely infertility was required he would have obtained such opinion. As it was he was not given that clear information by the clinic.

99. I have already indicated that the clinic failed to fulfil its obligations to Mr Brewer. As a consequence he was deprived of relevant information and the opportunity to meet the requirements of Regulations 4(3) or 7(3). The Authority has recognised this, and has sought by its guidance of 31 May 2012 to ensure that other providers and clinics do not fall into the same trap.

100. The failure of the clinic produced a great and conspicuous unfairness to Mr Brewer, and by extension, to Mrs Warren.

101. The Authority, while sympathetic to Mrs Warren says that Mr Brewer did not give his consent as required by Regulations 4(3)(a) or 7(3)(a); and that although Mr Spooner provided an opinion the contents of which they do not seek to challenge in any way, it was provided after death and thus does not fulfil Regulations 4(3)(b) or 7(3)(b) which uses the present tense "is prematurely infertile, or likely to become so".

102. The Authority says that the Regulations were carefully considered before being laid before Parliament, and that the Court should not override the Regulation or dilute the safeguards provided by them.

103. One thing is clear is that neither the Regulations nor Statute make any provision as to what should occur where there has been a clear failure by the clinic to give relevant information and the opportunity to the gamete provider to fulfil the requirements of Regulations 4 and 7.

104. If the gametes are allowed to perish at the end of the statutory period of 10 years that is the end of the matter. There is no come-back, no retrieval of the situation. It would be contrary to Mr Brewer's known intentions and wishes and a devastating loss to

Mrs Warren in the event of her wishing to bear his child. Without doubt it would be grossly and conspicuously unfair to her.

105. The Authority do not want the Regulations to be "diluted". The Authority wants the Regulations to stand untrammelled by the Court. The Authority wants clarity.

106. However, from a practical point of view the reality is that there could be a comparatively small number of cases and individuals in similar situations.

107. To override the Regulations would not involve large numbers of the population. Given the new Guidance of the Authority in May 2012 many of those in a similar position as Mr Brewer by now should have been given proper information and advice, and the potential for a similar situation arising as in this case diminished. I cannot say the potential would have been excluded, but the potential for such cases may well have been considerably reduced, and following my Judgment there would be further opportunities for clinics to reconsider their own practice. Thus, the chances of a case like this arising again should have been and may well be much reduced.

108. The issue is whether I should override the Regulations, as requested by Mrs Warren.

The Human Rights Act 1998

109. Mrs Warren in making her application for the Declaration which would override the Regulations relies upon the Human Rights Act 1998 Section 3 and Article 8.

110. Entitled "Interpretation of Legislation"

Section 3 of the HRA provides:

> *(1) So far as it is possible to do so primary legislation and subordinate legislation must be read and given effect in a way which is compatible with the Convention rights.*

111. Article 8 of the Convention states:

> *1. Everyone has the right to respect for his private and family life;*
>
> *2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic wellbeing of the country, for the prevention of disorder of crime, for the protection of health or morals or for the protection of the rights and freedom of others.*

112. I was referred to the cases of *Ghaidon v Godin-Mendoza 2004 2 AC 557* and *Evans v The United Kingdom 2008 43 EHRR 2.*

113. In his speech in *Ghaidon* Lord Nicholls of Birkenhead at paragraph 26:

> "Section 3 is a key section in the Human Rights Act 1998. It is one of the primary means by which Convention rights are brought into the law of this country. Parliament has decreed that all legislation existing and future shall be interpreted in a particular way. All legislation must be read and given effect to in a way which is compatible with the Convention rights "so far

> as it is possible to do so". This is the intention of Parliament, expressed in Section 3, and the courts must give effect to this intention."

at paragraph 30:

> "….. in the ordinary course the interpretation of legislation involves seeking the intention reasonably to be attributed to Parliament in using the language in question. Section 3 may require the court to depart from this legislative intention that is, depart from the intention of the Parliament which enacted the legislation. The question of difficulty is how far, and in what circumstances. Section 3 requires a court to depart from the intention of the enacting Parliament. The answer to this question depends upon the intention reasonably to be attributed to Parliament in enacting Section 5."

paragraph 32:

> "…… Section 3 enables language to be interpreted restrictively or expansively. But Section 3 goes further than this. It is also apt to require a court to read in words which change the meaning of the enacted legislation so as to make it convention compliant. In other words the intention of Parliament in enacting Section 3 was that to an extent bounded only by what is "possible" a court can modify the meaning and hence the effect of primary and secondary legislation."

114. Lord Steyn in his speech, at paragraph 41:

> "The second factor may be an excessive concentration on linguistic features of the particular statute. Nowhere in our legal system is a literalistic approach more inappropriate than when considering whether a breach of a Convention right may be removed by interpretation under Section 3. Section 3 requires a broad approach concentrating, amongst other things in a purposive way on the importance of the fundamental right involved."

at paragraph 46:

> "……. it was envisaged that the duty of the Court would be to strive to find (if possible) a meaning which would best accord with Convention rights. This is the remedial scheme which Parliament adopted."

115. The *Evans* case concerned two parties who having been in a relationship had parted company. During their relationship embryos had been created with the man's consent, which he had then withdrawn, and the woman who through illness had become infertile wished to use.

116. The Court said at paragraph 71:

> "It is not disputed between the parties that Article 8 is applicable and that the case concerns the applicant's right to respect for her private life. The Grand Chamber agrees with the Chamber that "private life" which is a broad term encompassing, inter alia, aspects of an individual's physical and social identity including the right to personal autonomy, personal development and to establish and develop relationships with other human beings and the outside world, incorporates the right to respect for both the decisions to become and not to become a parent."

paragraph 72:

> "It must be noted however that the applicant does not complain that she is in any way prevented from becoming a mother in a social, legal or even physical sense since there is no rule of domestic law or practice to stop her from adopting a child or even giving birth to a child originally created in vitro from donated gametes. The applicant's complaint is more precisely that the consent provisions of the 1990 Act prevent her from using the embryos she and J created together, thus given her particular circumstances from ever having a child to whom she is genetically related. The Grand Chamber considers that this more limited issue, concerning the right to respect for the decision to become a parent in the genetic sense also falls within the scope of Article 8.
>
> 73. The dilemma central to the present case is that it involves a conflict between the Article 8 rights of two private individuals …… if the applicant is permitted to use the embryos J will be forced to become a father whereas if his withdrawal of consent is upheld the applicant will be denied the opportunity of becoming a genetic parent …….
>
> 74. In addition the Grand Chamber, like the Chamber, accepts the Governments submission that the case does not invoke simply a conflict between individuals; the legislation in question also served a number of wider public interests in upholding the principle of the primacy of consent and promoting legal clarity and certainty."

At paragraph 90:

> "The Grand Chamber does not consider that the applicants right to respect for the decision to become a parent in the genetic sense should be accorded greater weight than J's right to respect of his decision not to have a genetically-related child with her."

Discussion

117. The case before me does not involve any conflict of individuals' rights. The evidence indicates that both Mr Brewer and his wife were in agreement. He wanted her to have the opportunity to have his child, if she wanted, after his death.

118. The difficulty before the Court is that the written consents provided by Mr Brewer did not specify that his gametes should be stored beyond the statutory period as required by the Regulations even though his consent for the use of his gametes by his wife after his death and his further consent that he be named as the father of any child so created were not time limited.

119. Mrs Warren relies on Article 8 in that she has the right to decide to become a parent by her deceased husband, which would accord with his wishes, and the written consent he gave. He never withdrew his consents either for storage, use by her or naming him.

120. I accept the proposition that she has this right and that this right should be respected by the state.

121. I have already said that he was not given the relevant information or the opportunity to give his consent for storage beyond the statutory period.

122. If the Regulations are wholly binding and cannot be interpreted in a purposive way his gametes would be allowed to perish in April/May 2015.

123. Mrs Warren told me she wanted to maintain her option until such time as she felt able to decide whether she wishes to undergo treatment and become a parent of her husband's child. She is neither psychologically, financially or practically ready to make that decision, and will not be able to do so within the time available. Indeed, she was advised that if she was to use the gametes before April 2015 to ensure as far as is possible a successful pregnancy she would have had to have commenced treatment by now. I add that even if she had commenced treatment and successfully given birth there is insufficient time for her to attempt a second pregnancy.

124. Mrs Warren says that to refuse her application for a Declaration would constitute a disproportionate interference with her Article 8 rights, and would not strike a fair balance.

125. If she were able to exercise her rights beyond April/May 2015 it would not violate anyone else's rights, it would not involve or endanger public safety, national security, or public health or morals. It would be purely a private matter for herself and one in which she is supported by her husband's family.

126. I have accepted she has the right under Article 8 to be able to decide to seek to become a parent by her deceased husband.

127. I also consider there is no reason other than the requirements of the Regulations to refuse this right.

128. The speeches in *Ghaidon* made it clear that the Court "if possible" under Section 3 of the Human Rights Act should look at the intention of Parliament in enacting the

legislation and interpret the legislation with a broad approach "concentrating …… in a purposive way on the importance of the fundamental right involved" per Lord Steyn, paragraph 41.

129. The primary legislation, being the Act, recognised and provided for the ability of a deceased man's gametes to be used by his widow to create an embryo, and hopefully a successful pregnancy. Regulations were made to provide a system of management and safeguards.

130. The 2009 Regulations, particularly Regulations 4 and 7 provide safeguards: the provider of the gametes must give written consent for storage beyond 10 years; a medical practitioner must certify that the donor is or is likely to be prematurely infertile.

131. Mr Brewer clearly by word and document indicated the wish to give his widow the opportunity to have his child after his death.

132. Dr Spooner's opinion, albeit written after his death, provides the necessary medical criteria. Mr Brewer had been referred to the clinic by this oncologist before he received radiotherapy, because it was known he could be rendered thereby prematurely infertile. The few documents available indicate that the clinic, he and Mrs Warren knew this was the reason for the referral, and no issue has ever been raised this was not the reason for the referral.

133. The 2009 Regulations refer to the maximum storage period of 55 years involving a ten yearly renewal of the medical criteria.

134. The Authority relies on Regulations 4(3)(b) and 7(3)(b) using the word "is". If the Regulations are interpreted strictly a medical certificate could only be provided during a man's lifetime and would only have a maximum of 10 years' validity. Thus if a man died within the 10 years lifetime of the medical certificate the medical criteria could not be extended beyond that period. Likewise the storage of sperm could not be extended beyond that time.

135. A strict interpretation could produce a very restrictive outcome. In my view this does not tally well with "up to the maximum period of 55 years".

136. Parliament intended to enable a deceased man's sperm to be used by the named person, in this case his widow, provided it was the deceased's wish recorded in writing.

137. The deceased's wish and intention is known, be it all not recorded in accordance with the Regulations in circumstances I have outlined.

138. The medical evidence, in particular the content of Dr Spooner's letter, as to the deceased's infertility or likely infertility is accepted.

139. I must interpret the statutory provisions in a purposive way and if possible interpret those provisions in a way which is compatible with Mrs Warren's Convention right under Article 8 to decide to seek to become a parent by her deceased husband.

140. Of course, there needs to be legal clarity and certainty. The Authority has recognised the "mischief" into which the clinic fell, and entrapped Mr Brewer. It has sought to warn and advise clinics of the dangers of their practice by its letter of May 2012.

141. In reality, although I cannot and do not know any figures, the number of cases which may arise are relatively few.

142. I am satisfied the State, through the Authority or by this Court should not interfere in Mrs Warren's right under Article 8, and that the statutory provisions, particularly the 2009 Regulations 4 and 7 should be interpreted with purpose to include the words "was, or may have been likely to become prematurely infertile".

143. On this basis it is right and proper, and proportionate for me to make the Declaration as sought, and in the first instance to say it is lawful for Mr Brewer's gametes to be stored for ten years beyond the opinion of Dr Spooner, dated 17 April 2013, namely to 17 April 2023.

144. Thereafter if there was appropriate medical opinion provided as to Mr Brewer's infertility in life the storage could be continued for a further period or periods up to a maximum of 55 years from April 2005.

145. Accordingly, I make the Declaration sought by Mrs Warren.

146. I add I am most grateful to Mrs Warren's Leading Counsel, Junior and solicitors who I understand acted pro bono on her behalf.

147. I would also like to express my sympathies to Mrs Warren and Mr Brewer's parents. They have suffered a great loss. They all loved Mr Brewer and suffered through his illness and death. I wish them all well and happiness in the future.